REMARKS

The Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the claims

Claims 1-10, 13-15, and 17-26 are withdrawn.

Claims 11, 12 and 16 are requested to be canceled without disclaimer or prejudice thereof.

Withdrawn claims 15, 17 and 18 are amended. The amendments add no new matter. Support for the amendments can be found throughout the specification, in the originally filed claims and, for example, at paragraphs [0248] and [0251].

Claims 27-31 are being added. The new claims add no new matter and exemplary support for the claims can be found, *inter alia*:

Claim	Exemplary Support
27	Paragraph [0248], [0797]
28	Paragraph [0759], [0779], [0788]
29	Paragraph [0251], [0797]
30	Paragraph [0759], [0779], [0788]
31	Paragraph [0777], [0800]

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-10, 13-15, 17-31 are now pending in this application.

II. Amendment to the title

The Office Action asserted that the title was not descriptive. (Office Action at page 3). Although the Applicants disagree with this assessment, to expedite prosecution, the title has been amended to recite "Novel Protein Expressed in Brain."

III. Claim Objections

Claim 16 is objected to for depending from non-elected claim 15. Claim 16 has been canceled thereby obviating the rejection.

IV. Claim rejection – non-obviousness type double patenting

The Office Action asserts that claims 11, 12, and 16 are unpatenable over claims 1-3, 9, 10 and 13 of U.S. Patent No. 6,475,753 (hereinafter the '753 Patent) on the grounds of non-statutory obviousness-type double patenting. (Office Action at page 4). Claims 11, 12, and 16 have been canceled, thereby obviating the rejection. New claims 27-31 are patentable over the claims 1-3, 9, 10 and 13 of the '753 Patent for at least the following reasons.

Claims 1-3, 9, 10 and 13 of the '753 Patent recite an isolated protein of SEQ ID NO: 161 which is at least 353 amino acids in length. None of the presently claimed polypeptides include 353 or more contiguous amino acids of SEQ ID NO: 161.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

V. Claim rejection – 35 U.S.C. § 112, first paragraph, enablement

Claims 11, 12, and 16 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to meet the enablement requirement. Specifically, the Office Action asserts that while the specification is "enabling for an isolated polypeptide having the amino acid sequence set forth in SEQ ID NO: 161, [the specification] does not reasonably provide enablement for a polypeptide at least 95% identical to the polypeptide of SEQ ID NO: 161 or a variant...." (Office Action at page

5). While the Applicants disagree with the Office Action analysis, solely to expedite prosecution, claims 11, 12 and 16 have been canceled, thereby obviating the rejection. New claims 27-31 meet the enablement requirements for at least the following reasons.

New claims 27 and 29 recite specific polypeptides derived from SEQ ID NO: 161. These polypeptides are disclosed and fully described in the specification (*see e.g.*, paragraphs [0246]-[0253]). Accordingly, one skilled in the art could easily make such a polypeptide without undue experimentation – the complete sequences are provided. Uses for such polypeptides are also detailed in the specification. For example, paragraphs [0251], [0252], and [0789]-[1084] describe methods of making peptides and antibodies, and methods of using these molecules in assays and for therapeutic purposes.

Similarly, new claims 28 and 30 are also enabled; that is, one skilled in the art could easily substitute a single amino acid of any of the claimed polypeptides and test for antibody binding, using for example, specific, pre-characterized antibodies. Such routine screening cannot be construed as "undue experimentation." And, identical to the peptides of claims 27 and 29, descriptions of how to use such peptides are detailed throughout the specification.

Finally, the peptides of claim 31 are also enabled. Methods to generate fusions proteins are well know in the art, and the amino acid sequences for the "first region" of the fusion peptides are provided in the specification. The second region of the peptide may be selected based on a pre-determined or desired function of the fusion peptide. As one example, the specification describes antigenic fusions and their uses:

As one of skill in the art will appreciate, and as discussed above, the polypeptides of the present invention comprising an immunogenic or antigenic epitope can be fused to other polypeptide sequences. For example, the polypeptides of the present invention may be fused with the constant domain of immunoglobulins (IgA, IgE, IgG, IgM), or portions thereof (CH1, CH2, CH3, or any combination thereof and portions thereof) resulting in chimeric polypeptides. Such fusion proteins may facilitate purification and may increase half-life in vivo. This has been shown for chimeric proteins consisting of the first two domains of the human CD4-polypeptide and various domains of the constant regions of the heavy or light chains of mammalian immunoglobulins. See, e.g., EP 394,827; Traunecker et al., Nature, 331:84-86 (1988). Enhanced delivery of an antigen across the epithelial barrier to the immune system has been demonstrated for antigens (e.g., insulin) conjugated to an FcRn binding partner such as IgG or Fc fragments (see, e.g., PCT Publications WO 96/22024 and WO 99/04813). IgG Fusion proteins that have a disulfide-linked dimeric structure due to the IgG portion disulfide bonds have also been found to be more efficient in binding and neutralizing other molecules than monomeric polypeptides or fragments thereof alone. See, e.g., Fountoulakis et al., J. Biochem., 270:3958-3964 (1995). Nucleic acids encoding the above epitopes can also be recombined with a gene of interest as an epitope tag (e.g., the hemagglutinin ("HA") tag or flag tag) to aid in detection and purification of the expressed polypeptide. For example, a system described) by Janknecht et al. allows for the ready purification of non-denatured fusion proteins expressed in human cell lines (Janknecht et al., 1991, Proc. Natl. Acad. Sci. USA 88:8972-897). In this system, the gene of interest is subcloned into a vaccinia recombination plasmid such that the open reading frame of the gene is translationally fused to an amino-terminal tag consisting of six histidine residues. The tag serves as a matrix binding domain for the fusion protein. Extracts from cells infected with the recombinant vaccinia virus are loaded onto Ni2+nitriloacetic acid-agarose column and histidine-tagged proteins can be selectively eluted with imidazole-containing buffers.

(Specification at paragraph [0800]). Accordingly, methods to make and use the polypeptides of claim 31 are more than adequately described. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

VI. Claim rejection – 35 U.S.C. § 112, first paragraph, written description

Claims 11 and 12 are rejected under 35 U.S.C. § 112 first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action asserts that there is insufficient characterization of the genus of polypeptides having at least 95% sequence identity to SEQ ID NO: 161, variants of SEQ ID NO: 161, and homologues of SEQ ID NO: 161. (Office Action at page 7). The Office Action continues, asserting that "only isolated polypeptides comprising the amino acid sequences set forth in SEQ ID NO: 161 or an isolated polypeptide encoded by sequence included in ATCC Deposit No: 209782 ... meets the written description provision...." (Office Action at page 9). Although the Applicants disagree with the Office Action assertions, solely to expedite prosecution, claims 11 and 12 have been canceled, thereby obviating the rejection. New claims 27-31 meet the written description requirement–that is, one skilled in the art would understand that the Applicants possessed the claimed invention at the time of filing–for at least the following reasons.

The sequence of the polypeptides of claims 27 and 29 are detailed in the specification at paragraphs [0248] and [0251]. Polypeptides that vary by a single amino acid are described, *inter alia*, at paragraph [0768]. Fusion peptides are described, *inter alia*, at paragraph [0800]. Accordingly, claims 27 and 29 recite "only isolated polypeptides comprising the amino acid sequences set forth in SEQ ID NO: 161 or an isolated polypeptide encoded by sequence included in ATCC Deposit No: 209782," and all other aspects of the polypeptides of claims 28 and 30-31 are presented and detailed in the specification. Thus, the pending claims meet the written description requirements of 35 U.S.C. § 112, and reconsideration and withdrawal of the rejection is respectfully requested.

VII. Claim rejection – 35 U.S.C. § 112, first paragraph, enablement

Claims 11-12 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to meet the enablement requirement because the specification allegedly does not include complete ATCC deposit information for the deposit of the cDNA. (Office Action at pages 9-10). Claims 11-12 have been canceled, thereby obviating the rejection, and new claims 27-31 do not recite the ATCC deposit information. Rather, new claims are directed to specific sequences detailed in the specification and presented in SEQ ID NO: 161. Accordingly, the pending claims meet the enablement requirements of 35 U.S.C. § 112, first paragraph, and reconsideration and withdrawal of the rejection is respectfully requested.

VIII. Claim rejection – 35 U.S.C. § 112, second paragraph

Claims 11 and 12 are rejected under 35 U.S.C. §112 second paragraph as allegedly being indefinite. Specifically, the Office Action asserts that the phrase "having biological activity" is unclear. (Office Action at page 11). Claims 11 and 12 have been canceled, and none of new claims 27-31 include the phrase "having biological activity." Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

IX. Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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